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09/980,120	11/30/2001	Marie-Christine Missana	P21742	8264

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EXAMINER
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ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/11/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/980,120

Applicant(s)

MISSANA ET AL.

Examiner

DAVID J ISABELLA

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

***Amendment Before First Office Action***

Preliminary Amendment filed on 5/9/02 was not filed along with the original application and therefor does not enjoy the status of part of the original disclosure. See MPEP 714.09

***Drawings***

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on May 9, 2002 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.121(f) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support the showing of the character lines to x', and alpha'.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24,25,27,32-36,41,42,48-63,74 and 75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification as filed fails to provide support for the claims as is now amended. Listed below are some illustrative examples. It is applicant's responsibility to review the original specification and point out support for all changes in the current amendments to the specification. It is clear from applicant's amendment that the changes to the specification were not merely to correct syntax and grammatical errors that may have carried over in the translation from the foreign application. It is clear that the current amendments to the specification seek to broaden out the scope of original disclosure of this application.

Examiner has pointed out various amendments made by applicant that attempt to broaden out the scope of the originally filed specification.

Changes in the body of Appendices 2-4 do not introduce new matter into the original specification.

Changes in the body of Appendix 5 appears to be replete with the introduction of new matter. In this appendix, applicant has replaced original terms such as "the nipple", "the front outer edge", the front upper edge", "the inner edge C", the rear outer edge A" with terms like "nipple area", "lower zone", "inner zone", "upper zone", "outer zone". Moreover applicant has replaced definite dimensions such as "EC:", "ED", "EA", "EA", "E" with the broader terms of "first", "second", "third", "fourth", "fifth" distances. Most importantly applicant has attempted to broaden out the numerical ranges as originally defined in the specification. In some instances, applicant has removed the "or equal to" from the phrase "of less than or equal to". In other instances, applicant has removed

language directed to the narrowing of the ranges by omitting the terms

"advantageously", "especially comprised" and "the preferred". Applicant has also

amended the specific to replace the term "is" with "may be", thereby broadening out the yes scope of the original disclosure.

The recitation of "The posterior surface, and the anterior surface form an angle <sup>see original claim 1</sup> (beta) in the inner zone of less than 70 degrees" is not consistent with the original specification. The original specification defines the planes P7 and P8 tangent to the anterior surface and to the posterior surface, respectively, of the pouch, once it is filled and in the implantation position at the inner edge C, form therebetween an angle less than or equal to 70 degrees. Nowhere in the specification can the examiner find support for the anterior and posterior surfaces forming an angle (beta) in the inner zone of less than 70 degrees. Clearly applicant is attempting to broaden out the specification to define the angle (beta) directly to the anterior and posterior surfaces without the use of a tangent at inner edge C. Moreover the original specification defines the angle (beta) as being less than or equal to 70 degrees and not "less than 70 degrees" as amended.

The recitation of "the soft pouch may be asymmetrical in relation to a plane which passes through an upper zone of the soft pouch, a nipple area of the soft pouch and a lower zone of the soft pouch" is clearly broader than applicant's original disclosure of the same. Applicant's original disclosure defines the plane P1 passing by the nipple E (not nipple area) and by the lower D and upper B front edges (not lower zone and upper zone).

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The recitation of "the asymmetry may be defined by a difference in dimensions between a first distance and a second distance defined by a plane passing through the inner zone, the nipple area and the outer zone, whereby the plane passing through the inner zone, the nipple area and the outer zone is perpendicular to a plane passing through the upper zone, the nipple area and the lower zone is clearly broader than applicant's original disclosure of the same. The original specification defines the asymmetry as "a difference in dimensions between the projection of the distance EC between the nipple and the front inner edge and the projection of the distance EA between the nipple and the front outer edge. The projections being made along a plane P2 perpendicular to the plane P1 passing by the aforementioned nipple and containing the nipple E as well as the front upper edge B.

\* broadening  
the zone  
encompassing

The recitation of "the first distance may be different from the second distance" finds no support in the original specification which defines that there is a difference in the two projections.

} yes

Nowhere in the original specification is there support for the amended language of "the first distance may be defined.... And the second distance may be defined..."

The specific recitation of "A ratio  $r$  of the second distance to the first distance" is not supported in the original specification which merely defines that "the ratio between these two projections is advantageously less than or equal to 0.95. Moreover the original specification defines the range of the ratio as further narrowing whereas applicant has amended the specific to remove the narrowing of the ranges by omitting the terms "advantageously", "especially comprised" and "the preferred".

There is not support for “the prosthesis may further comprise a third distance being defined between an edge of the rear outer zone and a point in the nipple area, whereby the first distance is defined between the point in the nipple area and an edge of the inner zone, the first and the third distance being at least one of equal to each other and very close to each other.

The changes to the paragraph related to the outer overlap portion fails to specifically include plane P5 tangent at k...with plane P6. Moreover, the original specification defines the range of the ratio as further narrowing whereas applicant has amended the specific to remove the narrowing of the ranges by omitting the terms “advantageously”, “especially comprised” and “the preferred”.

There is no support for the amendment that the “posterior surface may be at least one of concave and curved”.

Applicant’s amendment of “distance between a plane extending through an edge of the inner zone and an edge of the outer zone and a parallel plane extending through a point on the posterior surface that is farthest away from the plane extending through the edge of the inner zone and the edge of the outer zone may be at least 5 mm” clearly departs from the original specification that defines the same as “a first concave curvature is provided in a horizontal plane P3, this plane passing by the inner edge C, for example. In this case, the perpendicular projection GG’ of the pole G of the posterior surface on the horizontal plane P4 containing the outer rear edge A’ and the inner edge C, is at least 3 mm, especially at least 5 mm or 1cm, for example 0.8-1.5 cm. Nowhere in the original specification does the applicant define the plane as being

Examiner's arguments as set forth in the preceding paragraphs are equally applicable to paragraphs 3-7 on page 36 of appendix 5.

Nowhere in the original specification is there support for the language of “may be at least one of concave and curved”.

Examiner's arguments as set forth in the preceding paragraphs are equally applicable to paragraph 4on page 37 of appendix 5.

Amendment language of “may be one of less deformable and more rigid” is different than the original disclosure of “more rigid, less deformable” which is not in the alternative language as found in applicant’s amendment.

With respect to paragraph 5 on page 37 of appendix 5, see similar arguments pertaining to angle (beta) supra.

With respect to paragraph 6 on page 37 of appendix 5, the original specification does not provide support for the amendments of "may be adapted to be filled with the filling material either before or after" and "may comprise an expansion prosthesis".



With respect to paragraph 1 on page 38 of appendix 5, see similar arguments pertaining to angle (beta) supra.

With respect to paragraph 2 on page 38 of appendix 5, see similar arguments pertaining to corresponding subject matter supra.

Amendment to Appendix 7, "angles (alpha) and (alpha')" is not supported by the original specification and drawings

Amendment to Appendix 8, "angles x and x' are each" is not supported by the original specification and drawings.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is indefinite. Line 4 change "comprising" to "having--". Lines 8 and 9 are redundant.

Claim 23 fails to further define the prosthesis of claim 22. Claim 22 does not positively set forth the filling material in the body of the claim.

Claim 25 fails to define the first and second distances. *OK*

Claim 26 is redundant.

Claim 28 should be reworded as –no greater than 0.95–.

~~Claim 32 is meaningless.~~

Claim 33, see rejection to claim 32 supra.

Claim 34 fails to define the fourth and fifth distances. *OK*

Claim 35 is redundant.

Claim 37 is redundant.

Claim 41 is meaningless. What constitutes an overlap portion.

Claims 42-47, see rejection to claim 41 supra.

Claim 48, it is not clear what is being claimed. If the surface is concave, then it is curved.

Claim 49, see rejection to claim 48 supra.

Claim 50, see rejection to claim 48 supra.

Claim 51, it is not apparent how one is to determine a point that is farthest from the plane extending through the edge of the inner zone and the edge of the outer zone.

Claim 52, see rejection to claim 51 supra.

Claim 53, see rejection to claim 48 supra

Claim 54, see rejection to claim 48 supra.

Claims 55-57, see rejection to claim 51 supra.

Claim 58, see rejection to claim 48 supra.

Claims 59-60, see rejection to claim 51 supra.

Claim 61, it is not clear what constitutes "another portion".

Claim 62 is meaningless.

Claim 73 is meaningless.

Claim 74, see rejection to claim 22 supra.

Claim 75, the nipple zone as defined is indefinite. It is not clear how each parts have different volumes.

Contrary to applicant's arguments, the rejections are not made based upon breadth of the claims. The claims are, de facto, indefinite as per the previous office action.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perras et al (3665520) in view of Schweikhart (GB 2146692).

Perras, et al discloses an implantable breast prosthesis that is asymmetric including a soft pouch filled with a filling material. The pouch has anterior, posterior, inner and outer surfaces. The posterior surface is concave and the anterior surface is convex. Perras, et al is silent as to the specific angles delineated by the surfaces and the edges of the prosthesis. Schweikhart teaches the use of an implantable insert for the breast that is configured to match the configuration of the shape of the breast tissue and the human thorax in the breast region. Schweikhart teaches the specific angles as claimed. Since Perras, et al is silent as to the specific angles delineated by the surfaces, one with ordinary skill in the art would look to Schweikhart as a reference to formulate the prosthesis so as to best match the natural breast tissue and the human thorax in the breast region.


Moreover, the claims attempt to define zones and distances obliquely. Since the claims fail to specifically locate the various zones, points and between edges, the examiner may interpret any zones, points and between edges that would meet the broadness of the claimed limitations. Since Perras, et al as modified discloses a prosthesis having the angles as claimed, then the zones, points, planes and distances between various edges and arbitrary points are inherent in the structure of Perras, et al. The language of the claim "which is specific to either a right breast side or left breast side" does not preclude the breast prosthesis as disclosed by Perras et al as modified. Applicant narrow interpretation of the reference does not support the language of the claims. The claim fails to positively define that the breast prosthesis is asymmetrical

which is specific to either a right side or left side. As broadly worded, the claims do not preclude the prosthesis of Perras, et al as modified.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3579 for regular communications and 703-305-3580 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

dji  
February 9, 2004